

WHAT IS CLAIMED IS:

1. An electrochemical cell for use in sampling biological fluid and measuring an analyte therein, the cell comprising:
 - (a) a first electrode; and
 - (b) a second electrode positioned concentrically within and spaced-apart from the first electrode and comprising a distal end configured to pierce a skin surface.
2. The electrochemical cell of claim 1 wherein the first electrode comprises a continuous wall configuration having an open distal end and a distal edge.
3. The electrochemical cell of claim 2 wherein the continuous wall comprises a cylindrical configuration and the distal edge define a skin-contacting surface.
4. The electrochemical cell of claim 1 wherein the second electrode has an elongated configuration having a length that is co-axial with the first electrode.
5. The electrochemical cell of claim 1 further comprising an insulator positioned within at least a portion of the space between the first and second electrodes.
6. The electrochemical cell of claim 1 wherein the first and second electrodes have the same length.
7. The electrochemical cell of claim 1 wherein the first and second electrodes have different lengths.
8. The electrochemical cell of claim 7 wherein the first electrode is shorter than the second electrode.

9. The electrochemical cell of claim 7 wherein the first electrode is longer than the second electrode.
10. The electrochemical cell according to claim 1 wherein the second electrode has a penetration length no deeper than the dermis.
11. The electrochemical cell according to claim 10 wherein the second electrode has a penetration length no deeper than the epidermis.
12. The electrochemical cell of claim 2 wherein the space between the electrodes has a thickness sufficient to exert a capillary force on fluid present at the open distal end of the first electrode.
13. The electrochemical cell of claim 12 wherein the thickness is in the range from about 250 to 1500 μm .
14. The electrochemical cell of claim 1 wherein the biological fluid is interstitial fluid or blood and the analyte is glucose.
15. The electrochemical cell according to claim 1 further comprising a reagent material in contact on a surface of at least one of the electrodes.
16. The electrochemical cell according to claim 1 wherein the first electrode comprises a skin-contacting surface at a distal end for exerting pressure on the skin surface adjacent the distal end of the second electrode.
17. The electrochemical cell according to claim 16 wherein the skin-contacting surface has a ring configuration.

18. A device for sampling a biological fluid and measuring a target constituent within the biological fluid, comprising:

- an inner electrode having a proximal end, a distal end and a length therebetween;
- an outer electrode having a cylindrical configuration comprising a proximal end, an open distal end and a lumen coaxially spaced-apart from the inner electrode;
- an insulating material coaxially conformed between a portion of the proximal ends of the inner and outer electrodes; and
- a skin-lancing member extending from the distal end of the inner electrode.

19. The device of claim 18 wherein the facing surfaces of the inner and outer electrodes and the insulating material defines a reaction chamber having dimensions sufficient to exert a capillary force on fluid present at the distal ends of the electrodes.

20. The device of claim 18 wherein the inner electrode comprises a base portion extending radially inward from the proximal end thereof.

21. The device of claim 18 further comprising a signal producing and receiving means in electrical communication with the electrodes.

22. A system for sampling biological fluid from the skin of a patient and measuring a target constituent within the biological fluid, the system comprising:

(a) an electrochemical cell comprising a first electrode and a second electrode spaced-apart from each other, wherein the first electrode is positioned concentrically about the second electrode and the second electrode comprises a distal end configured to pierce a skin surface; and

(b) a control unit in electrical communication with the electrochemical cell, comprising:

- (1) means for sending an electrical reference signal to the first electrode and for receiving an electrical output signal from the second electrode, and

(2) a software algorithm which automatically calculates and determines the concentration of the target constituent in the biological sample upon receipt of the electrical output signal.

23. The system according to claim 22 further comprising a display unit in electrical communication with the control unit for displaying information in the form of electrical signals received from the control unit related to the sampling of the biological fluid and the measuring of the target constituent.

24. The system according to claim 22 further comprising a housing and a support means wherein the control unit is housed within the housing and the at least one electrochemical cell is mounted to the support means.

25. The system of claim 22 comprising an array of electrochemical cells.

26. A method for testing a biological fluid within the skin of a patient and for determining the concentration of a target constituent contained therein, the method comprising the steps of:

providing an electrochemical cell comprising a concentrically spaced-apart inner and outer electrodes, wherein the inner electrode comprises a lancing member;

inserting the lancing member into the skin to a selected depth wherein biological fluid exits from the skin;

transferring a sample of biological fluid into the electrochemical cell;

providing a first electrical signal to the electrochemical cell; and

receiving a second electrical signal generated by the electrochemical cell, wherein the second electrical signal is representative of the concentration the constituent in the sample.

27. A method according to claim 26 wherein the selected depth is no greater than the dermis.

28. The method according to claim 27 wherein the selected depth is no greater than the viable epidermis.

29. The method according to claim 28 wherein the selected depth is no greater than the stratum corneum.

30. A method according to claim 26 wherein the step of transferring comprises exerting a capillary force on the sampled biological fluid.

31. A method according to claim 26 wherein the steps of providing a first electrical signal and receiving a second electrical signal is performed by a control unit in electrical communication with the electrochemical cell.

32. A method according to claim 28 further comprising the step of deriving the concentration of the constituent in the patient's biological fluid from the second electrical signal.

33. The method according to claim 32 further comprising the step of displaying a numerical value representative of the concentration of the constituent in the patient's biological fluid.

34. The method according to claim 32 wherein the step of deriving comprises using a software algorithm.

35. A kit for sampling a biological fluid from the skin of a patient and for measuring the concentration of a constituent within the sampled biological fluid, the kit comprising:

at least one electrochemical cell according to any of claims 1 to 17.

36. The kit according to claim 35 comprising a plurality of electrochemical cells and a support member wherein the plurality of electrochemical cells are arranged in an array on the support member.

37. The kit according to claim 36 wherein the inner electrodes of the plurality of electrochemical cells have varying penetration lengths.

38. The kit according to claim 35 further comprising one or more reagents for facilitating the measurement of one or more constituents within the sampled biological fluid.